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10/056,063	01/28/2002	M. Clark Dale	P66143US1	3968

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EXAMINER

LILLING, HERBERT J

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 05/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/056,063

Applicant(s)

DALE ET AL.

Examiner

HERBERT J LILLING

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 4-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 4-17 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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1. Receipt is acknowledged of the amendment filed April 17, 2003.

2. Claims 1-17 remain pending in this application.

This application contains claims 4-17 drawn to an invention nonelected with traverse in Paper No. 5. A complete reply to the final rejection must include **cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.**

In view of the fact that Applicant has not advanced prosecution in view of the claims of record and the arguments submitted, Applicant is required to be in compliance with the above. However, this Examiner will allow method claims to be rejoined with any microorganism claimed subject matter that will render the application be allowed with the next response to the following Final Rejection.

The restriction requirement has been made **FINAL**.

3. All of the prior rejections of the previous office action have been fully maintained in view of the lack of suitable information and arguments to withdrawn any of the previous rejections, which have been recited as follows:

"4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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A. Claim 1 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

B. Claims 1-3 stand rejected for the following:

It is apparent that the strain(s) is/(are) required to practice the claimed invention(s) as recited in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of all strains. See 37 C. F. R. 1.802.

The specification does not provide a repeatable method for obtaining the strain(s) and it does not appear to be a readily available material. Deposit of the strain(s) would satisfy the enablement requirements of 35 U.S.C. 112. If a deposit has been made, Applicant is required to meet the necessary criteria of the deposit rules in accordance with 37 CFR 1.801-37 CFR 1.809.

If a deposit has not been supplied or made under the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty **and that all restrictions** imposed by the depositor on the availability to the public of the deposited material will be **irrevocably removed** upon the granting of a patent, would satisfy the deposit requirements, See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

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b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;

c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

d) a viability statement in accordance with the provisions of 37 CFR 1.807;

and

e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification, See 37 CFR 1.803-37 CFR 1.809 for additional explanations of these requirements.

Applicant is required to be in full compliance with U.S. Rules of Deposits with respect to the availability of the strain. Upon receipt of a statement pertaining to the above (b): that all **restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent. This requirement is a difference between the U.S. Rules and the Budapest Treaty. Upon receipt of statement pertaining to the availability, the above rejection will be withdrawn and Claims 2-3 will be allowed.**

C. Claim 1 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The broad generic claim one lacks sufficient description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing since the specification lacks a sufficient number of strains that have been described in the specification, thus the description requirement has not been satisfied for Claim 1.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as anticipated by US 4560659, Asturias: Ethanol production from fermentation of sugar cane, December 24, 1985

or, in the alternative, under 35 U.S.C. 103(a) as obvious over Asturias.

The cited reference discloses a *Saccharomyces cerevisiae* strain, which appears to be identical to the presently claimed strain, since it contains the same properties as admitted. Absent a showing to the contrary, the referenced microorganism appears to be identical to the presently claimed strain which includes the claimed different properties absent a showing to the patentable alleged differences and is considered to anticipate the claimed microorganism since the strain produces ethanol and has the same properties. Consequently, the claimed strain appears to be anticipated by the reference in view of:

It is well settled that if a reference reasonably teaches a product that is identical or substantially identical or are produce by identical or substantially identical process, the PTO can

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require an applicant to prove that the prior art products do not inherently possess the characteristics of his claimed product. A rationale given for shifting the burden of going forward to applicant is that the PTO does not possess the facilities to manufacture or to obtain and compare prior art products, see In re Brown, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972); In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977).

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed strain would have been obvious to those of ordinary skill in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

6. No claim is allowed. "

#### Response to Applicant's Arguments and Amendments to Specification and Claims

##### **Remarks pertaining to Page 2:**

Applicant has inserted inherent properties for the claimed deposited strain. These properties are functional properties that depend upon the specific reaction conditions of the experimental conditions. The characteristics and morphological taxonomic properties for the deposited strain as well as the generic strain have not been submitted on the record. The properties are comparative or functional which renders the distinguishing characteristics not in complete compliance with the guidelines as indicated above:

"...the identifying information set forth in 37 CFR 1.809(d) should be added to the specification, See 37 CFR 1.803-37 CFR 1.809 for additional explanations of these requirements."

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The rejection of the claims as noted by paragraph "4. A" as "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention " stands in view of the above paragraph pertaining to the ".... characteristics and morphological taxonomic properties for the deposited strain as well as the generic strain have not been submitted on the record. "

The issue is that applicant has **FAILED TO PARTICULARLY POINT OUT AND DISTINCTLY CLAIM THE SUBJECT MATTER.**

**Remarks are pertaining to Page 3:** The specification lacks sufficient Taxonomic and Characteristics for the claimed deposit. In addition, Applicant is not in compliance with the U.S. Rules of Deposit with respect to the following as indicated in the previous Office Action:

"Applicant is required to be in full compliance with U.S. Rules of Deposits with respect to the availability of the strain. Upon receipt of a statement pertaining to the above (b): that all **restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent. This requirement is a difference between the U.S. Rules and the Budapest Treaty."**

**Remarks pertaining to Page 3 part C rejection:**

It is absolutely clear that the rejection has been based on the fact the instant application does not support the subject matter commensurate in scope with the claimed language. The specification lacks sufficient description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing since the specification lacks a sufficient number of strains that have been described in the specification, thus the description requirement has not been satisfied for Claim 1. The claim is exceptionally broad drawn to functional language that is dependent upon fermentation conditions. Applicants have argued "The characteristics set forth in claim 1 are inherent characteristics of the subject matter to which the entire application is directed. Being in possession of the strain having these inherent characteristics, Applicants unquestionably had possession of the invention called for by claim 1." The issue that the specification does not teach no more than the isolation of one specific deposited strain but the claimed subject matter is drawn to characteristics that are broader than the enabling disclosure as well as the specification does not support the written description commensurate in scope with the claimed subject matter.

Applicant has argued the following point in their attempt to overcome the rejection based on prior art:

Applicant has alleged that the prior art is not satisfactory for the following reasons as **stated on page 5:**

"This contrasts with Applicants" yeast strain which is narrowly critical to the practice of the invention; strain BPSC-15/NRRL 306730 [error 30630] is the only strain, to

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Applicant's knowledge, able to form such stable floc pellets, release very few free yeast cells in to the fermentation medium, and ferment sugars in such high osmolality solutions as desired in the application." The remarks indicate that the specification teaches that the yeast is "**the only strain**" to meet the conditions. Thus, Claims 1 and 3 are duplicates of the deposited strain.

**Remarks pertaining to rejection of claim 1 under 35 U.S.C. 102 (b):**

The rejection of the claim stands as stated in the absence of a showing that the reference strain is not within the scope of the functional language of the claimed language. The arguments are drawn to comparisons drawn to different methods and Applicant has failed to show a comparative difference drawn to the same process conditions. The Examples employed do not encompass the same conditions and one of ordinary skilled in the art would have expected differences. Applicant is required to indicate at least one single intrinsic difference in the properties of the two strains [patented reference vs. instant BPSC-15/NRRL 30630 strain] or a showing of one comparative procedure demonstrating a difference due to the strains per se. The Table submitted on page 7 does not show any direct comparison or any intrinsic property difference. The arguments and showings, pages 7-9, have been deemed not to be sufficient to overcome the rejection.

**Remarks pertaining to the restriction pages 9-10:**

The restriction has have been considered in the above paragraph 2. This Examiner will be in full compliance **with rejoining** any process or method claims commensurate in scope with any microorganism product that is allowed.

4. **No claim is allowed.**

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Examiner Lilling whose telephone number is (703) 308-2034** and **Fax Number** is for applications **Before Final** (703) 872-9306 and **After Final** for applications is 703-872-9307 or SPE Michael Wityshyn whose telephone number is (703) 308-4743. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

H.J.Lilling: HJL

(703) 308-2034

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May 13, 2003

  
Dr. Herbert J. Lilling  
Primary Examiner  
Group 1600 Art Unit 1651